

MAR 3 0 2001

K010652

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

**1. Submitter, name, address, contact**

Sigma Diagnostics Inc.  
545 South Ewing Ave  
St. Louis, MO 63103

Contact person: William R. Gilbert  
(314) 286-6693

Date Prepared: March 2, 2001

**2. Device name**

Proprietary name: SIGMA-CAL™

Common name: Calibrator

Classification name: Calibrator, Multi-analyte mixture

**3. Predicate device**

Roche Diagnostics Calibrator for Automated Systems (C.f.a.s.)

**4. Device description**

Assayed, liquid preparation containing analytes (human and non-human) in a human serum base. Preservative added.

**5. Intended Use**

Sigma Diagnostics SIGMA-CAL calibrator is intended for use in the calibration of automated chemistry analyzers.

## 6. Comparison to predicate device

### Similarities

Characteristic	SIGMA-CAL™ (Candidate Device)	Roche Diagnostics C.f.a.s. (Predicate Device)
Intended Use	For use in the calibration of automated chemistry analyzers.	For use as a calibrator of clinical chemistry assays for automated analytical procedures.
Format	Human Sera Based, with constituents added as required to obtain desired component concentrations.	Human Sera Based, with constituents added as required to obtain desired component levels.
Stability	Stable at 2-8 °C until expiration date	Stable at 2-8 °C until expiration date
Levels	Single level	Single level
Analytes	Albumin, Bilirubin (total), Calcium, Bicarbonate, Chloride, Cholesterol, Creatinine, Glucose, Magnesium, Phosphorus, Potassium, Protein (total), Sodium, Triglycerides, Urea nitrogen (BUN), Uric acid	Albumin, Bilirubin (total), Calcium, Bicarbonate, Chloride, Cholesterol, Creatinine, Glucose, Magnesium, Phosphorus, Potassium, Protein (total), Sodium, Triglycerides, Urea nitrogen (BUN), Uric acid

### Differences

Characteristic	SIGMA-CAL™ (Candidate Device)	Roche Diagnostics C.f.a.s. (Predicate Device)
Format	Liquid	Lyophilized
Analytes		Acid phosphatase Alkaline phosphatase Alanine aminotransferase α-Amylase Aspartate aminotransferase Cholinesterase Creatine kinase γ-Glutamyltransferase Iron Lactate dehydrogenase LD1 Lipase UIBC



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 30 2001

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

William R. Gilbert, Ph.D.  
Manager, Scientific Affairs  
Sigma Diagnostics, Inc.  
545 South Ewing Avenue  
St. Louis, MO 63103

Re: K010652  
Trade Name: Sigma Diagnostics SIGMA-CAL™  
Regulatory Class: II  
Product Code: JIX  
Dated: March 2, 2001  
Received: March 5, 2001

Dear Dr. Gilbert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in cursive script that reads "Steven Gutman".

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health


Enclosure

510(k) Number (if known): K010652

Device Name: Sigma Diagnostics SIGMA-CAL™

### Indications For Use:

Sigma Diagnostics SIGMA-CAL™ is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens.

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K010652

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use